

Message Text

PAGE 01 STATE 100751

14-11
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 COME-00 EB-07 /031 R

66607
DRAFTED BY: DHEW/FDA:JRWEINROTH, MD
APPROVED BY: OES/SCI/BMP: MBEAUBIEN
DHEW/OIH:MACODDING
EUR/NE:CLFLOYD (INFO)
EUR/WE:WHMARSH (INFO)

----- 114571

R 302135Z APR 75
FM SECSTATE WASHDC
TO AMEMBASSY PARIS
AMEMBASSY LONDON

UNCLAS STATE 100751

E.O. 11652: N/A
TAGS: ETRD, EIND, TBIO, FR, UK
SUBJECT: FDA ADVISORY - INADEQUATELY LABELED AND DEFECTIVE MEDICAL
DEVICE

1. FDA ADVISES THAT THE TRIPLE ISOLATED PRECISION PHYSIOLOGICAL
PRESSURE TRANSDUCER, MODEL NO. 4-327-1 MANUFACTURED BY BELL
AND HOWELL, ELECTRONICS AND INSTRUMENTS GROUP, INSTRUMENTS
DIVISION, 360 SIERRA MADRE VILLA, PASADENA, CALIF. 91109 IS
CONSIDERED TO BE INADEQUATELY LABELED AND DEFECTIVE FOR THE FOLLOWING
REASON; THE PRODUCT CASING IS MADE OF PLASTIC AND THE INSTRUCTIONS
STATE THAT THE DEVICE CAN BE STEAM AUTOCLAVED. HOWEVER, WHEN
THE DEVICE IS STEAM AUTOCLAVED, THE PLASTIC PARTS DEFORM, THEREBY
RENDERING THE PRODUCT NO LONGER USABLE. THE FIRM IS RECALLING
THE DEVICE TO THE USER (HOSPITAL) LEVEL.

2. POSTS ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES ARE
FAMILIAR WITH DETAILS OF RECALL.

3. FOREIGN CONSIGNEES AS FOLLOWS:

BELL AND HOWELL, S.A., ZONE SILIL, CIDEX L138, 94533 RUNGIS,
UNCLASSIFIED

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FRANCE

BELL AND HOWELL, LTD. ALPERTON HOUSE, WEMBLY, MIDDLESEX,
ENGLAND KISSINGER

UNCLASSIFIED

<< END OF DOCUMENT >>

Message Attributes

Automatic Decaptioning: X
Capture Date: 18 AUG 1999
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: n/a
Control Number: n/a
Copy: SINGLE
Draft Date: 30 APR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE100751
Document Source: ADS
Document Unique ID: 00
Drafter: DHEW/FDA:JRWEINROTH, MD
Enclosure: n/a
Executive Order: N/A
Errors: n/a
Film Number: n/a
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t197504101/abbrznsx.tel
Line Count: 57
Locator: TEXT ON-LINE
Office: n/a
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: ShawDG
Review Comment: n/a
Review Content Flags:
Review Date: 10 JUL 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <10 JUL 2003 by leeperne>; APPROVED <11 FEB 2004 by ShawDG>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - INADEQUATELY LABELED AND DEFECTIVE MEDICAL DEVICE
TAGS: ETRD, EIND, TBIO, FR, UK
To: PARIS
LONDON
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006